

vapor pressure of pure water at the same temperature.

§ 431.2 Containers and closures.

(a) *Examination and handling of empty containers.* (1) Empty containers, closures, and flexible pouch roll stock must be evaluated by the establishment to ensure that they are free of structural defects and damage that may affect product or container integrity. Such an examination should be based on a statistical sampling plan.

(2) All empty containers, closures, and flexible pouch roll stock must be stored, handled, and conveyed in such a manner that will prevent damage that could affect the hermetic condition of the sealed container.

(3) Just before filling, rigid containers must be cleaned to prevent incorporation of foreign matter into the finished product. Closures, semirigid containers, preformed flexible pouches, and flexible pouch roll stock contained in original wrappings do not need to be cleaned before use.

(b) *Closure examinations for rigid containers (cans)*—(1) *Visual examinations.* A closure technician must visually examine the double seams formed by each closing machine head. When seam defects (*e.g.*, cutovers, sharpness, knocked down flanges, false seams, droops) are observed, necessary corrective actions, such as adjusting or repairing the closing machine, must be taken. In addition to the double seams, the entire container must be examined for product leakage or obvious defects. A visual examination must be performed on at least one container from each closing machine head, and the observations, along with any corrective actions, must be recorded. Visual examinations must be conducted with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations must be made by the closure technician at the beginning of production, immediately following every jam in the closing machine and after closing machine adjustment (including adjustment for changes in container size).

(2) *Teardown examinations.* Teardown examinations of double seams formed

by each closing machine head must be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing head must be examined on the packer's end during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, must be promptly recorded by the closure technician. The establishment must have container specification guidelines for double seam integrity on file and available for review by Program employees. A teardown examination of the can maker's end must be performed on at least one container selected from each closing machine during each examination period except when teardown examinations are made on incoming empty containers or when, in the case of self-manufactured containers, the containers are made in the vicinity of the establishment and the container plant records are made available to Program employees. Additional teardown examinations on the packer's end should be made at the beginning of production, immediately following every jam in a closing machine and after closing machine adjustment (including adjustment for a change in container size). The following procedures must be used in teardown examinations of double seams:

(i) *Dimensional measurement.* One of the following two methods must be employed for dimensional measurements of the double seam.

(A) *Micrometer measurement.* (1) For cylindrical containers, measure the following dimensions (Figure 1 to § 431.2) at three points approximately 120 degrees apart on the double seam excluding and at least one-half inch from the side seam juncture:

- (i) Double seam length—W;
- (ii) Double seam thickness—S;
- (iii) Body hook length—BH; and
- (iv) Cover hook length—CH.

(2) Maximum and minimum values for each dimensional measurement must be recorded by the closure technician.

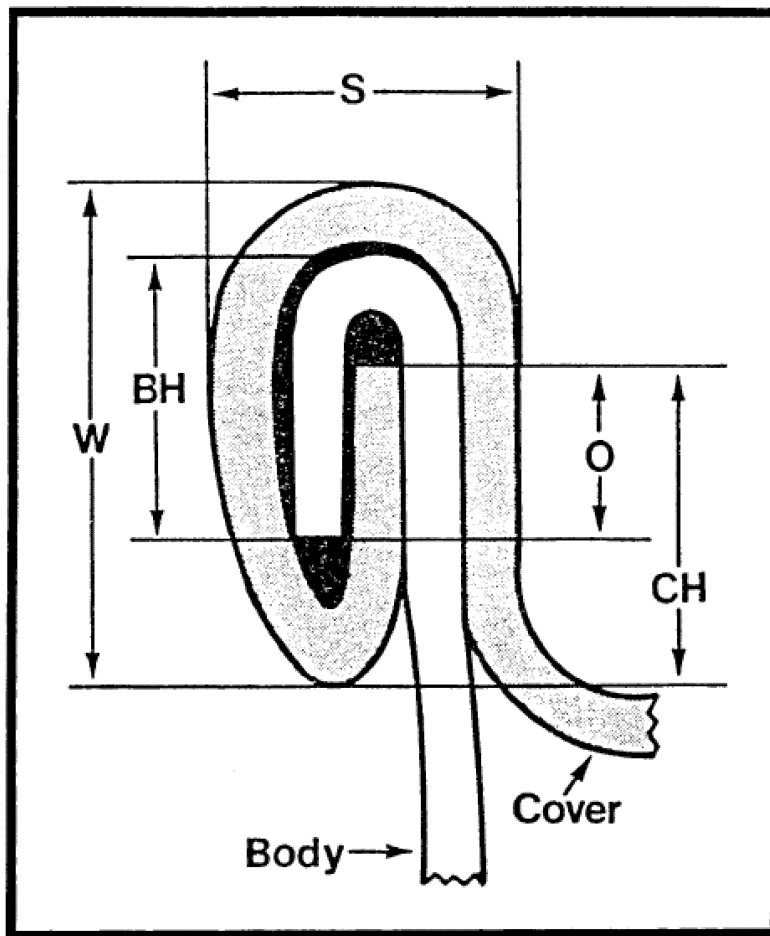


Figure 1 to § 431.2—Micrometer Measurement of Cylindrical Containers

(B) *Seamscope or seam projector.* Required measurements of the seam include thickness, body hook, and overlap.

(ii) *Seam thickness.* Seam thickness must be obtained by micrometer. For cylindrical containers, at least two locations, excluding the side seam juncture, must be used to obtain the required measurements.

(iii) *Seam tightness.* Regardless of the dimensional measurement method used to measure seam dimensions, at a min-

imum, the seam(s) examined must be stripped to assess the degree of wrinkling.

(iv) *Side seam juncture rating.* Regardless of the dimensional measurement method used to measure seam dimensions, the cover hook must be stripped to examine the cover hook droop at the juncture for containers having side seams.

(v) *Examination of noncylindrical containers.* Examination of noncylindrical containers (e.g., square, rectangular,

“D”-shaped, and irregularly-shaped) must be conducted as described in paragraphs (b)(2)(i), (ii), (iii), and (iv) of this section except that the required dimensional measurements must be made on the double seam at the points listed in the establishment's container specification guidelines.

(c) *Closure examinations for glass containers*—(1) *Visual examinations*. A closure technician must visually assess the adequacy of the closures formed by each closing machine. When closure defects, such as loose or cocked caps, fractured or cracked containers and low vacuum jars, are observed, necessary corrective actions, such as adjusting or repairing the closing machine must be taken and recorded. In addition to the closures, the entire container must be examined for defects. Visual examinations must be made with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations must be made by the closure technician and the observations recorded at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(2) *Closure examinations and tests*. Depending upon the container and closure, tests must be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made either before or after thermal processing and at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing machine must be examined during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, must be promptly recorded by the closure technician. The establishment must have specification guidelines for closure integrity on file and available for review by Program employees. Additional closure examinations should be made at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (in-

cluding adjustment for a change in container size).

(d) *Closure examinations for semi-rigid and flexible containers*—(1) *Heat seals*—

(i) *Visual examinations*. A closure technician must visually examine the seals formed by each sealing machine. When sealing defects are observed, necessary corrective actions, such as adjusting or repairing the sealing machine, must be taken and recorded. In addition to examining the heat seals, the entire container must be examined for product leakage or obvious defects. Visual examinations must be performed before and after the thermal processing operation and with sufficient frequency to ensure proper closure. These examinations should be conducted at least in accordance with a statistical sampling plan. All defects noted and corrective actions taken must be promptly recorded.

(ii) *Physical tests*. Tests determined by the establishment as necessary to assess container integrity must be conducted by the closure technician at a frequency sufficient to ensure proper closure. These tests must be performed after the thermal processing operation and should be made at least every 2 hours of continuous production. The establishment's acceptance guidelines for each test procedure must be on file and available for review by Program employees. Test results along with any necessary corrective actions, such as adjusting or repairing the sealing machine, must be recorded.

(2) *Recording*. Double seams on semirigid or flexible containers must be examined and the results recorded as provided in paragraph (b) of this section. Any additional measurements specified by the container manufacturer must also be made and recorded.

(e) *Container coding*. Each container must be marked with a permanent, legible, identifying code mark. The mark must, at a minimum, identify in code the product (unless the product name is lithographed or printed elsewhere on the container) and the day and year the product was packed.

(f) *Handling of containers after closure*. (1) Containers and closures must be protected from damage which may cause defects that are likely to affect

the hermetic condition of the containers. The accumulation of stationary containers on moving conveyors should be minimized to avoid damage to the containers.

(2) The maximum time lapse between closure of containers and initiation of thermal processing must be 2 hours unless data are available from the establishment's processing authority demonstrating that an alternative time period is safe and will not result in product spoilage.

§ 431.3 Thermal processing.

(a) *Process schedules.* Prior to the processing of canned product for distribution in commerce, an establishment must have a process schedule (as defined in § 431.1) for each canned meat or poultry product to be packed by the establishment.

(b) *Source of process schedules.* (1) Process schedules used by an establishment must be developed or determined by a processing authority.

(2) Any change in product formulation, ingredients, or treatments that are not already incorporated in a process schedule and that may adversely affect either the product heat penetration profile or sterilization value requirements must be evaluated by the establishment's processing authority. If it is determined that any such change adversely affects the adequacy of the process schedule, the processing authority must amend the process schedule accordingly.

(3) Complete records concerning all aspects of the development or determination of a process schedule, including any associated incubation tests, must be made available by the establishment to the Program employee upon request.

(c) *Submittal of process information.* (1) Prior to the processing of canned product for distribution in commerce, the establishment must provide the inspector at the establishment with a list of the process schedules (including alternate schedules) along with any additional applicable information, such as the retort come-up operating procedures and critical factors.

(2) Letters or other written communications from a processing authority recommending all process schedules

must be maintained on file by the establishment. Upon request by Program employees, the establishment must make available such letters or written communications (or copies thereof). If critical factors are identified in the process schedule, the establishment must provide the inspector with a copy of the procedures for measuring, controlling, and recording these factors, along with the frequency of such measurements, to ensure that the critical factors remain within the limits used to establish the process schedule. Once submitted, the process schedules and associated critical factors and the procedures for measuring (including the frequency), controlling, and recording of critical factors must not be changed without the prior written submittal of the revised procedures (including supporting documentation) to the inspector at the establishment.

§ 431.4 Critical factors and the application of the process schedule.

Critical factors specified in the process schedule must be measured, controlled, and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule. Examples of factors that are often critical to process schedule adequacy may include:

(a) *General.* (1) Maximum fill-in weight or drained weight;

(2) Arrangement of pieces in the container;

(3) Container orientation during thermal processing;

(4) Product formulation;

(5) Particle size;

(6) Maximum thickness for flexible containers, and to some extent semirigid containers, during thermal processing;

(7) Maximum pH;

(8) Percent salt;

(9) Ingoing (or formulated) nitrite level (ppm);

(10) Maximum water activity; and

(11) Product consistency or viscosity.

(b) *Continuous rotary and batch agitating retorts.* (1) Minimum headspace; and

(2) Retort reel speed.

(c) *Hydrostatic retorts.* (1) Chain or conveyor speed.

(2) [Reserved]